DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 172, 176-179, 181-186, 188, 190-193, 195-197, 199, 200, 202-205, 207-209, and 211 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 7,754,697 in view of Cowsert et al. (US 5,580,767, of record). Claims 1 and 2 of '697 recite:

> 1. A double-stranded synthetic DNA gene, comprising multiple copies of a structural gene region, wherein the structural gene region comprises a nucleotide sequence which consists of greater than 20 consecutive nucleotides and which is identical to a nucleotide sequence of a target gene in a eukaryotic cell, wherein one of the copies is placed in the sense orientation and another of the copies is placed in the antisense orientation operably under the control of a single promoter sequence which is operable in the cell, wherein the copy of the structural gene region placed in the sense orientation and the copy of the structural gene region placed in the antisense orientation are arranged so as to form an interrupted palindrome sequence which is operably under the control of the single promoter sequence, and wherein the structural gene region placed in the sense orientation and the structural gene region placed in the antisense orientation are separated by a sequence of nucleotides that is 50-100 nucleotides in length or 100-500 nucleotides in length.
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> 2. The double-stranded synthetic DNA gene of claim 1, wherein the target gene is from a viral pathogen of a vertebrate animal cell.

The claims of '697 also recite an animal cell comprising the construct and method of using the construct.

However, the claims of '697 do not specifically teach a target gene selected from viral DNA polymerase, viral RNA polymerase, or a viral coat protein.

At the time the invention was made, Cowsert teaches an oligonucleotide for inhibiting RNA polymerase to reduce the proliferation of a virus (column 3). It is

acknowledged that Cowsert is directed to making and using a nucleic acid inhibitor possibly with a different mechanism of inhibiting/reducing expression of a gene, then the mechanism for double stranded construct as claimed by Graham et al. Thus, one of ordinary skill in the art would have been obvious to try using the target gene for other nucleic acid inhibitors and studying whether there is an improvement using dsRNA compared to known nucleic acid inhibitor against the target gene.

In addition, at the time the invention was made, viral DNA polymerase and viral coat proteins were known to one of ordinary skill in the art for initiation of the disease or pathology of a virus. This would lead one of ordinary skill in the art to select a target gene selected from a viral pathogen, e.g., virus comprising a viral DNA polymerase, viral RNA polymerase, or a viral coat protein because these genes are required for initiation of pathology. Thus, one of ordinary skill in the art could make a construct comprising a nucleotide sequence targeting expression of a viral polymerase with a reasonable expectation of success.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of the claims of '697 taken with Cowsert et al., namely to produce and use the claimed product. One of ordinary skill in the art would have been motivated to combine the teaching to study the inhibition of expression of a viral RNA polymerase of a virus in a mammalian cell infected with the virus and/or if it is more efficient than antisense oligonucleotides at inhibiting expression of a viral RNA polymerase. "The combination of familiar elements according to known

methods is likely to be obvious when it does no more than yield predictable results." See ***KSR v. Teleflex***, 550 U.S. 398, 127 S. Ct. 1727 (2007).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the claims of '697 taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a lentivirus. One of ordinary skill in the art would have been motivated to combine the teaching to improve and/or study the efficiency of inhibiting the virus.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the claims of '697 taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of an immunodeficiency virus. One of ordinary skill in the art would have been motivated to combine the teaching to improve and/or study the efficiency of inhibiting the virus.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the claims of '697 taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a virus, wherein the gene is in an exon. One of ordinary skill in the art would have been motivated to combine the teaching to improve and/or study the efficiency of inhibiting the virus by targeting the exon.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the claims of '697 taken with Cowsert,

namely to produce an isolated mammalian cell comprising liposome or viral particle comprising a construct comprising a structural gene encoding RNA polymerase of a virus. One of ordinary skill in the art would have been motivated to combine the teaching since both are commonly used by one of ordinary skill in the art to successfully deliver a nucleic acid to a cell.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 6/28/11 have been fully considered but they are not persuasive. 37 CFR 1.321 (c)(3) requires that a TD "Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

The words "legal title" do not include common ownership as to equitable title.

Claims 172, 176-179, 181-186, 188, 190-193, 195-197, 199, 200, 202-205, 207-209, and 211 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 225-294 of copending Application No. 10/346,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set claims read on a similar double stranded DNA construct and method of using the construct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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The words "legal title" do not include common ownership as to equitable title.

Claims 172, 176-179, 181-186, 188, 190-193, 195-197, 199, 200, 202-205, 207-209, and 211 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 158-202 of copending Application No. 10/821,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set claims read on a similar double stranded DNA construct and method of using the construct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 6/28/11 have been fully considered but they are not persuasive. 37 CFR 1.321 (c)(3) requires that a TD "Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall

be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

The words "legal title" do not include common ownership as to equitable title.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number 571-272-0764. The examiner can normally be reached on Monday-Thursday from 6:30 to 4:00 (Eastern Standard Time). The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor Heather Calamita can be reached on 571 272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Brian Whiteman/

Primary Examiner, Art Unit 1635